



**PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Elmer M. Price

Serial No.: 10/808,248

Filed: March 24, 2004

For: METHOD OF TREATMENT OF

ENDOTHELIAL DYSFUNCTION AND ENGINEERED PROTEINS FOR SAME

Group Art Unit: 1614

Examiner: Unknown

Atty. Dkt. No.: UVMO:024US

CERTIFICATE OF MAILING 37 C.F.R 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to:, MS AM NDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or the date below:

January 12, 2005

Date

Steven .. Highlander

### INFORMATION DISCLOSURE STATEMENT

#### MS AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as

defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first

Official Action reflecting an examination on the merits, and hence is believed to be timely filed

in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the

filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R.

§§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the

Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit

Account No.: 50-1212/UVMO:024US.

Applicants respectfully request that the listed documents be made of record in the present

case.

Respectfully submitted,

Steven I. Highlander

Reg. No. 37,642

Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue, Suite 2400 Austin, Texas 78701 (512) 474-5201

Date:

January 12, 2005

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Form P	ГО-144	9 (modified)		Atty. Docket			al No.	
List of Patents and Publications for Applicant's				UVMO:024US		10/8	10/808,248	
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Form PTO-1449 (modified)		Atty. Docket No. UVMO:024US	Serial No. 10/808,248
List of Patents and Publications for A	Applicant's	Applicant	
		Elmer M. Price et al.	
Information Disclosure St	ATEMENT		
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	С9	Ferrario et al., "The hypertension-lipid connection: insights into the relation between angiotensin II and cholesterol in atherogenesis," Amer. J. Med. Sciences, 323:17-24, 2002.
•	C10	Forstermann et al., "Isoforms of nitric-oxide synthase: purification and regulation," Methods Enzymology, 233:258-265, 1994.
	C11	Frankel and Pabo, "Cellular uptake of the tat protein from human immunodeficiency virus," Cell, 55:1189-1193, 1988.
	C12	Frankel et al., "Dimerization of the tat protein from human immunodeficiency virus: a cysteinerich peptide mimics the normal metal-linked dimer interface," Proc. Natl. Acad. Sci., USA, 85(17):6297-6300, 1988.
	C13	Frankel et al., "Tat protein from human immunodeficiency virus forms a metal-linked dimer," Science, 240:70-73, 1988.
	C14	Garcia et al., "Functional domains required for tat-induced transcriptional activation of the HIV-1 long terminal repeat," EMBO J., 7(10):3143-3147, 1988.
	C15	Guerci et al., "Endothelial dysfunction and type 2 diabetes. Part 1: physiology and methods for exploring the endothelial function," <i>Diabetes Metab.</i> , 27(4pt1):425-434, 2001.
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	C17	Han et al., "Efficient intracellular delivery of GFP by homeodomains of Drosophila Fushitarazu and Engrailed proteins," Molecules and Cells, 10:728-732, 2000.
	C18	Hauber et al., "Mutational analysis of the conserved basic domain of human immunodeficiency virus tat protein," J. Virol., 63:1181-1187, 1989.
	C19	Hingorani, "Polymorphisms in endothelial nitric oxide synthase and athergogenesis," <i>Atherosclerosis</i> , 154:52 1-527, 2000.
	C20	Jain et al., "Enalapril acts through release of nitric oxide in patients with essential hypertension," Renal Failure, 23(5):651-657, 2001.
	C21	Jin et al., "Transduction of human catalase mediated by an HIV-1 TAT protein basic domain and arginine-rich peptides into mammalian cells," Free Rad. Biol. Med., 31(11):1509-1519, 2001.

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Exam. Init.	Ref. Des.	Citation
	C22	Kwon et al., "Transduction of Cu,Zn-superoxide dismutase mediated by an HIV-1 Tat protein basic domain into mammalian cells," FEBS Letters, 485:163-167, 2000.
	C23	Leber et al., "Characterization of recombinant human endothelial nitric-oxide synthase purified from the yeast Pichia pastoris," J. Biol. Chem., 274:37658-37664, 1999.
	C24	Lin et al., "Prolonged reduction of high blood pressure with human nitric oxide synthase gene delivery," Hypertension, 30(3pt1):307-313, 1997.
	C25	Lopez Farre and Casado, "Heart failure, redox alterations, and endothelial dysfunction," Hypertension, 38:1400-1405, 2001.
	C26	Luscher, "Vascular protection: current possibilities and future perspectives," <i>IJCP Supplement</i> , 117:3-6, 2001.
	C27	Maeso et al., "Effect of atorvastatin on endothelium-dependent constrictor factors in dyslipidemic rabbits," General Pharmacol., 34(4):263-272, 2000.
,	C28	Monacada et al., "The L-arginine-nitric oxide pa," New Engl. J. Med., 329:2002-2012, 1993.
	C29	Nagahara et al., "Transduction of full-length TAT fusion proteins into mammalian cells: TAT-p27Kip1 induces cell migration," Nature Medicine, 4:1449-1452, 1998.
	C30	Olsen <i>et al.</i> , "Endothelial dysfunction in resistance arteries is related to high blood pressure and circulating low density lipoproteins in previously treated hypertension," <i>Amer. J. Hypertension</i> , 14(9pt1):861-867, 2001.
	C31	Qian et al., "Nitric oxide synthase gene therapy rapidly reduces adhesion molecule expression and inflammatory cell infiltration in carotid arteries of cholesterol-fed rabbits," <i>Circulation</i> , 99:2979-2982, 1999.
	C32	Ruben et al., "Structural and functional characterization of human immunodeficiency virus tat protein," J. Virology, 63:1-8, 1989.
	C33	Sadaie et al., "Human immunodeficiency virus type 1 rev protein as a negative trans-regulator," DNA, 8(9):669-674, 1989.
	C34	Schwarze <i>et al.</i> , "In vivo protein transduction: delivery of a biologically active protein into the mouse," <i>Science</i> , 285:1569-1572, 1999.
	C35	Schwarze <i>et al.</i> , "In vivo protein transduction: intracellular delivery of biologically active proteins, compounds and DNA," <i>Trends in Pharmacol. Science</i> , 21:45-48, 2000.

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	C36	Suwaidi et al., "Long-term follow-up of patients with mild coronary artery disease and endothelial dysfunction," Circulation, 101:948-954, 2000.
	C37	Teupe et al., "Vascular gene transfer of phosphomimetic endothelial nitric oxide synthase (S1177D) using ultrasound-enhanced destruction of plasmid-loaded microbubbles improves vasoreactivity," Circulation, 105:1104-1109, 2002.
	C38	Torchilin et al., "TAT peptide on the surface of liposomes affords their efficient intracellular delivery even at low temperature and in the presence of metabolic inhibitors," Proc. Natl. Acad. Sci., USA, 98:8786-8791, 2001.
	C39	Vallance et al., "Nitric oxidefrom mediator to medicines," J. Royl. Coll. Physician London, 28:209-219, 1994.
	C40	Venema et al., "Role of the enzyme calmodulin-binding domain in membrane association and phospholipid inhibition of endothelial nitric oxide synthase," Amer. Soc. Biochem. Molec. Biol., 270:14705-14711, 1995.
	C41	Woodman et al., "Induction of nitric oxide synthase mRNA in coronary resistance arteries isolated from exercise-trained pigs," Am. J. Physiol., 273(6pt2):H2575-2579, 1997.
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	C43	Yap et al., "Distribution and function of recombinant endothelial nitric oxide synthase in transplanted hearts," Cardiovascular Res., 42(3):720-272, 1999.

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January 12, 2005

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L. Highlander

MS AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

RE:

U.S. Patent Application No. 10/808,248 entitled "METHOD OF TREATMENT OF

ENDOTHELIAL DYSFUNCTION AND ENGINEERED PROTEINS FOR SAME" - Elmer M.

Price et al.

Our reference: UVMO:024US Client reference: 02UMC062

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references C1-C43.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/UVMO:024US.

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Respectfully submitted,

Steven L. Highlander Reg. No. 37,642

SLH/mar

Encl: as noted